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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,984

05/25/2006

Curtis Dobson

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5866

50670

7590

06/30/2010

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

06/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/580,984	DOBSON, CURTIS	
	<b>Examiner</b>	<b>Art Unit</b>	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 13, 14 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 13, 14, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)                            |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application                  |
| Paper No(s)/Mail Date _____   | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Listing Error Report</u> |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-8, 10, 11, 13, 14 and 16-18 are pending.

Applicants' amendment filed April 22, 2010 is acknowledged. Applicants' response has been fully considered. Claims 1-8 and 18 have been amended. Claims 10, 11, 13, 14, 16 and 17 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1-8 and 18 are examined.

### **Withdrawn Informalities**

2. The previous objection to the specification regarding SEQ ID NO:2 and the sequences in Table 1 is withdrawn in view of applicants' amendment to the specification, and applicants' response at page 11 in the amendment filed April 22, 2010.

### **Withdrawn Claim Rejections - 35 USC § 101**

3. The previous rejection of claims 1-7 and 18 under 35 U.S.C. 101 is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 11 in the amendment filed April 22, 2010.

### **Withdrawn Claim Rejections - 35 USC § 112**

4. The previous rejection of claims 1-8 and 18 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 12-13 in the amendment filed April 22, 2010.

### **Withdrawn Claim Rejections - 35 USC § 102**

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5. The previous rejection of claim 2, under 35 U.S.C. 102(b) as being anticipated by Lunec *et al.* (WO 98/42751) is withdrawn in view of applicants' response at page 13 in the amendment filed April 22, 2010.

***Informalities-Sequence Listing***

The disclosure is objected to because of the following informalities:

6. Applicant has submitted a new version of Sequence Listing on April 22, 2010, however, this Sequence Listing has errors (See attached Sequence Listing Error Report) and could not be accepted. Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the Sequence Listing.

***Claim Objections***

7. Claims 3 and 7 are objected to because of the use of the term "SEQ ID No.". Use of the term "SEQ ID NO:" is suggested.

***Maintained Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8 and 18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1-8 and 18 are directed to a polypeptide, derivative or analogue thereof, comprising a tandem repeat of apolipoprotein B or a truncation thereof, characterized in that the tandem repeat or truncation thereof is obtained from an HSPG receptor binding region of apolipoprotein B; and a composition comprising the polypeptide, derivative or analogue thereof.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses that GIN16 (SEQ ID NO:48) has antiviral effect against HSV1 and some peptides comprising a tandem repeat from an HSPG receptor binding region of apolipoprotein B exhibit antiviral properties (pages 5-6, 11-12), the specification does not disclose a genus of variants for polypeptides, derivatives or analogues comprising a tandem

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repeat of apolipoprotein B or a truncation thereof, where the tandem repeat or truncation thereof is obtained from an HSPG receptor binding of apolipoprotein B, where the structures and functions of the peptide variants are not indicated. The specification does not sufficiently describe the whole genus of peptide variants when there is substantial structural variation within the genus with no defined function. Some species of antiviral peptides (listed on pages 11-12) do not provide sufficient written description for the whole genus of peptide variants obtained from an HSPG receptor binding of apolipoprotein B and including numerous analogs, derivatives and truncations with no defined structure and function. Without guidance on structure to function/activity of various peptides (e.g., analogs, derivatives and truncations) obtained from an HSPG receptor binding of apolipoprotein B, one skilled in the art would not readily identify a functional peptide. The lack of a structure to function/activity relationship for the peptides obtained from an HSPG receptor binding of apolipoprotein B, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

#### Response to Arguments

Applicants indicate that the specification provides sufficient detail to convey to one of ordinary skill in the art that applicant had possession of the claimed invention. For example, the specification describes more than "several species of antiviral peptides (listed on pages 11-12)." Pages 11-12 disclose 20 different peptides. Additionally, the specification provides a definition, by structure and formula (formulas I, II, III and IV) that is sufficient to distinguish it from other materials. The combination of this disclosure clearly conveys to one of ordinary skill in the art

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that Applicant had possession of the claimed invention at the time of the filing of the application.

In light of the foregoing, Applicants request reconsideration and withdrawal of this rejection (page 12 of the response).

Applicants' response has been fully considered, however, the arguments are not found persuasive because of the following reasons. While the specification discloses 20 different peptides ranging from 14 to 18 amino acids (at pages 11-12) and formulas I, II, III or IV (pages 9-11), the whole genus of claimed peptide variants including analogs, derivatives and truncations without defined structure and function would encompass numerous peptides with substantial structural variations, especially for derivatives and truncations. Without structure/function correlation of peptide variants, one skilled in the art cannot readily identify a functional peptide. For these reasons, applicants are not in possession of the claimed invention, and the rejection is maintained.

### ***Maintained Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lunec *et al.* (WO 98/42751).

Lunec *et al.* teach a molecule having the sequence of RLTRKRGLKLA or a partially modified form thereof or analog thereof inhibits uptake by the high affinity LDL receptor of LDL, and the sequence is residues 3359-3369 of apolipoprotein B 100 (the paragraph bridging

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pages 2 and 3), where the sequence of RLTRKRGLKLA comprises the instant SEQ ID NO:1, RLTRKRGLK and is a truncation of tandem repeat of human apolipoprotein B<sub>(3359-3367)</sub> having the amino acid sequence of SEQ ID NO:1, which meets the criteria of claims 1 and 3-4. Lunec *et al.* also teach a composition comprising the molecule and a pharmaceutically acceptable carrier (page 4, the fourth paragraph; claim 8).

#### Response to Arguments

Applicants indicate that Lunec *et al.* does not anticipate claims 1-4 and 8 because Lunec *et al.* does not disclose a polypeptide having a tandem repeat of the HSPG receptor binding region of apolipoprotein B as required by the claims. Therefore, the rejection should be withdrawn (page 13 of the response).

Applicants' response has been fully considered. Regarding claim 2, which is directed to a polypeptide comprising a tandem repeat of LDL receptor binding region of apolipoprotein B, applicants' argument is found persuasive, and the rejection is withdrawn. However, regarding claims 1, 3, 4 and 8, which encompass a polypeptide having a tandem repeat of the HSPG receptor binding region of apolipoprotein B or a truncation thereof, the arguments are not found persuasive because of the following reasons. Lunec *et al.* teach a molecule having the sequence of RLTRKRGLKLA, which comprises the instant the SEQ ID NO:1, RLTRKRGLK. The instant claims 1, 3, 4 and 8 recite a polypeptide comprising a tandem repeat of LDL receptor binding region of apolipoprotein B or truncation thereof, since the claims do not specifically define the truncation, the sequence of RLTRKRGLKLA taught by Lunec *et al.* can be considered as a truncation of tandem repeat of human apolipoprotein B<sub>(3359-3367)</sub>. Therefore, the rejection of claims 1, 3, 4 and 8 is maintained.



***Conclusion***

10. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

June 22, 2010